

REMARKS

These remarks are responsive to the Office Action mailed on October 10, 2008 (“the Office Action”). The Applicants thank the Examiner for a careful and thorough examination of the above-referenced Application.

Status of the Claims

At the time of the Office Action, claims 32-47, 112 and 115-135 were pending, with claims 32-47, 112 and 115-135 being rejected. Claims 32, 112, 117, 119, 121, 132, 133, 134, and 135 have been amended herein. Claims 136-144 have been added. Support may be found throughout the specification and claims, but especially at least in paragraphs 0022, 0028, 0069, 0086-0090, and 0092-0095, and Figures 8-11, 19, and 25. No new matter has been submitted.

Status of the Specification

Paragraphs 0087, 0088, and 0090 have been amended in response to objections to the drawings. The amendments merely concern reference characters. No new matter is submitted.

Drawings

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4), as reference character “38” allegedly refers to more than one element. Office Action, p. 2. Accordingly, the Applicants have amended Figures 22 and 25 and paragraphs 0087, 0088, and 0090 of the Specification. Appropriate replacement sheets are submitted herewith. In addition, with respect to the use of “force transducer,” “strain gauge,” and

“load or pressure transducer,” the Applicants respectfully note that these terms may be used interchangeably as noted in paragraph 0087.

The drawings are objected to as failing to comply with 37 C.F.R. § 1.84(p)(5) because reference numbers 38a, 38b, 38c, 41 and 43 are allegedly not mentioned in the description. Office Action, p. 2. Accordingly, Figures 22 and 25 are hereby amended, and appropriate replacement sheets submitted herewith. Reference numerals “38a,” “38b,” “38c,” and “43” have been removed from Figure 22. Reference numeral “41” has been redefined.

The Applicants respectfully submit that the drawings are now in compliance with 37 C.F.R. §§ 1.84(p)(4) and 1.84(p)(5), and request the Examiner to remove these objections.

Claim Objections

Claim 117 currently stands objected to for an alleged informality. Appropriate amendments are made herein. The Applicants respectfully request that this objection be withdrawn.

35 U.S.C. § 102 Rejections

Claims 32, 34, 38, 112, 115-119, 122, and 132-135 currently stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Harrington (U.S. Patent No. 5,893,889). Office Action, p. 4. “A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” M.P.E.P. § 2131. “Every element of the claimed invention must be literally present, arranged as in the claim.” *Richardson v. Suzuki Motor Co. Ltd.*, 868 F.2d 1226, 1236, 9 U.S.P.Q.2d 1913 (Fed. Cir. 1989). The claims must not be treated as

“mere catalogs of separate parts, in disregard of the part-to-part relationships set forth in the claims and that give the claims their meaning.” *Lindemann Maschinenfabrik GMBH v. American Hoist and Derrick Company et al.*, 730 F.2d 1452, 1459, 221 U.S.P.Q. 481 (Fed. Cir. 1984). As a result, a reference that coincidentally lists features of a claim without describing the claimed arrangement, relationship, and organization of such features cannot anticipate.

The amended independent claims require a projection having at least one side wall parallel to a longitudinal axis of the prosthesis (the “Projection Limitation”). Harrington teaches only upper and lower frustoconical surfaces 44, 58 in what the Examiner deems Harrington’s projections. The conical upper surface of Harrington’s lower endplate 34 is therefore angled steeply away from parallel. Such a design is not efficient in terms of enabling utilization of the empty interior space of the annular-shaped polymeric member for a second purpose, such as is accomplished in certain embodiments of the present invention (*i.e.*, utilizing empty interior space in which electronic components are enclosed). No portion of Harrington’s upper or lower endplate contains at least one side wall that is parallel to the longitudinal axis of the prosthesis. Therefore, Harrington cannot anticipate the claims because it wholly lacks the Projection Limitation.

The Applicants further point out that Harrington additionally fails to anticipate a spinal disc prosthesis having a first endplate having an upper surface and a relatively flat, uninterrupted lower surface (the “Surface Limitation”) as recited by the amended claims. As stated above, Harrington teaches two frustoconical surfaces 44, 58. These surfaces are discontinuous and interrupted. The lower surface 44 is interrupted by an opening that accepts threaded post 45. The upper surface 58 is interrupted by the neck 57 opening,

which accepts the post 45 and pivot ball therethrough. Both these structures constitute discontinuities in the surfaces. Harrington also discloses a tubular portion 50 that extends from the upper endplate shown in Figure 2. However, this tubular portion is also interrupted by the discontinuity for receiving the optional plug 69 and the pivot ball. Therefore, Harrington cannot anticipate the claims because it wholly lacks the Surface Limitation.

Moreover, Harrington could not be modified in an attempt to provide the Surface Limitation of the amended claims because doing so would defeat an essential feature of Harrington, namely employing a post received in a socket to keep the two portions of the prosthesis together. If the Harrington prosthesis were to be modified to comprise the simple flat uninterrupted surface described in the amended claims, it could not be held together as was Harrington's intention for the purposes of avoiding pain and injury to the patient. Harrington, Abstract; Col. 1, lines 55-56; Col. 2, lines 1-7; Col. 3, lines 37-47.

For at least the reasons set forth herein, Harrington fails to anticipate independent claims 32, 112, 119, and 133-135, and any claim depending therefrom. Thus, the Applicants respectfully request that this rejection be withdrawn.

35 U.S.C. § 103 Rejections

The Office Action set forth a multitude of § 103 rejections in varying combinations with regard to various claims. For the sake of simplicity, the following is a summary of the various 35 U.S.C. § 103 rejections.

- Claims 33, 35-37, 120 and 121: allegedly being unpatentable over Harrington.
Office Action, p. 10.

- Claims 39 and 123: allegedly being unpatentable over Harrington, and further in view of Ishikawa, et al. (U.S. Patent No. 6,447,448). Office Action, p. 11.
- Claims 40, 41, 124, and 125: allegedly being unpatentable over Harrington, in view of Ishikawa, and further in view of Kovacevic (U.S. Patent No. 5,197,488). Office Action p. 12.
- Claims 42 and 126: allegedly being unpatentable over Harrington, in view of Ishikawa, and further in view of Wanderman, et al. (U.S. Patent No. 5,511,561) and Medical Electronics Manufacturing (“MEM”). Office Action, p. 13.
- Claims 43, 46, 47, 127, 130 and 131: allegedly being unpatentable over Harrington, in view of Steffee (U.S. Patent No. 5,071,437). Office Action, p. 14.
- Claims 44 and 128: allegedly being unpatentable over Harrington, in view of Steffee, and further in view of Cauthen (U.S. Patent No. 6,179,874). Office Action, p. 15.
- Claim 45: allegedly being unpatentable over Harrington, in view of Steffee, and further in view of Cauthen, and further in view of Kenna (U.S. Patent No. 4,714,469) and Wang, et al. (U.S. Patent No. 4,714,468). Office Action, p. 16.
- Claim 129: allegedly being unpatentable over Harrington, in view of Steffee, and further in view of Kenna, and Wang. Office Action, p. 16.

In determining the differences between the claims and the prior art under Section 103, the question is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious. M.P.E.P. § 2141.02(I); *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1537, 218 U.S.P.Q. 871 (Fed. Cir. 1983); *Schenck v. Norton Corp.*, 713 F.2d 782, 785, 218 U.S.P.Q. 698 (Fed.

Cir. 1983). In order to properly use a reference for purposes of finding a claimed invention obvious, the reference must be considered in its entirety, as a whole, including portions that would lead away from the claimed invention. M.P.E.P. § 2141.03(VI); *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1550-53, 220 U.S.P.Q. 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984).

A. Claims 33, 35-37, 120 and 121

The Examiner alleges that Harrington renders obvious claims 33, 35-37, 120, and 121. As stated above, Harrington fails to disclose or suggest the Projection Limitation and the Surface Limitation. These limitations, or similar variants, are recited in all the amended independent claims of the present invention. And, as explained above, Harrington cannot be modified to include these limitations because to do so would fundamentally alter an essential feature of Harrington.

Harrington uses a pivot ball retained in a socket to prevent the ball from becoming removed from the socket. Harrington, Abstract; Col. 1, lines 55-56; Col. 2, lines 1-7; Col. 3, lines 37-47. Thus, modifying Harrington to remove the pivot ball and socket would change the principle of operation of Harrington and render it inoperable for its intended purpose. M.P.E.P. § 2145(IV). As a result, Harrington fails to render obvious claims 33, 35-37, 120, and 121.

B. Claims 39 and 123

The Examiner combined Ishikawa with Harrington in her rejection of claims 39 and 123. Ishikawa merely discloses spherical semiconductor balls for use in various medical implants. It provides no teaching with respect to any structure that could comprise the Projection Limitation. It provides no teaching with respect to any structure

that could comprise the Surface Limitation. And it does nothing to change the fact that Harrington cannot be modified to remove the pivot ball and socket in order to contain the Projection Limitation and the Surface Limitation. As a result, the Harrington/Ishikawa combination cannot render obvious claims 39 and 123.

C. Claims 40, 41, 124, and 125

The Examiner added Kovacevic to Harrington and Ishikawa in her rejection of claims 40, 41, 124, and 125. Kovacevic is directed to a knee prosthetic and a system for measuring dynamic forces. As a preliminary matter, the Examiner's combination for these claims uses Harrington and Ishikawa "as applied to claims 39 and 123 above". (Office Action, p. 12). The Applicants assume that the Examiner makes this §103 combination using the structural definitions she used in her Section 102 rejections.¹

As it turns out, however, it does not matter which structures of the combination the Examiner defines as the "endplates" or the "projections". Kovacevic, like Harrington and Ishikawa, fails to disclose any teaching of a structure that could comprise either the Projection Limitation or the Surface Limitation. And, as described above, it too does not change the fact that Harrington cannot be modified to remove the pivot ball and socket in order to contain the Projection Limitation and the Surface Limitation. Therefore, the combination of Harrington/Ishikawa/Kovacevic fails to render obvious claims 40, 41, 124, and 125.

¹ The Applicants note that the Examiner alternately assigned differing labels to different structures of Harrington for different claims of the present Application. For example, in the §102 rejection of claim 32, the Examiner stated that the first endplate is 34. But in her §102 rejection of claim 112, she defined the first endplate as 32. Because claims 40 and 41 depend from claim 32, and claims 124 and 125 depend from claim 119, the Applicants will use the Examiner's structural definitions for her rejections of claim 32 and 119, respectively. Both claims define the first endplate as "34" and the second endplate as "32".

D. Claims 42 and 126

The Examiner added Wanderman and MEM to Harrington and Ishikawa in her rejection of claims 42 and 126. Wanderman, *et al.* is directed to a foot-pad monitor to detect the amount of force transmitted through a heel. It contains no teaching whatsoever regarding the Projection Limitation or the Surface Limitation. MEM allegedly teaches that flex circuits can be used in medical implants. However, it too is silent as to structure akin to the Projection Limitation or the Surface Limitation. Neither Wanderman and MEM change the fact that Harrington cannot be modified to remove the pivot ball and socket in order to contain the Projection Limitation and the Surface Limitation. Therefore the Harrington/Ishikawa/Wanderman/MEM combination also fails to render obvious claims 42 and 126.

E. Claims 43, 44, 45, 46, 47, 127, 128, 129, 130, and 131

An Examiner's combination is improper if the proposed modifications would render the reference unsatisfactory for its intended purpose. M.P.E.P. § 2143.01(V). Similarly, if the proposed combination would change the principle operation of the reference, then there is no *prima facie* case of obviousness. M.P.E.P. § 2143.01(VI); M.P.E.P. § 2145(III). Simply put, it is improper to combine references where the references teach away from their combination. M.P.E.P. § 2145(X)(D)(2); *In re Grasselli*, 713 F.2d 731, 744-45, 218 U.S.P.Q. 769 (Fed. Cir. 1983).

Combining the Harrington and Steffee references is improper because it would render Steffee unsatisfactory for its intended purpose. Steffee teaches an artificial disc with no connection between the upper and lower plates except for the elastomeric core

therebetween. Steffee, Col. 2, lines 37-39; Col. 4, lines 23-25. Steffee further claims a disc prosthesis with an elastomeric core, “free of any cavity.” *Id.* at claim 1.

Harrington, however, comprises a connection between its plates in addition to the shock absorber, namely, the threaded post 46 and the relationship between the pivot ball and neck 57. The post 46 of Harrington is crucial to the design of Harrington, which addressed the problem of separation noted in prior art devices. Harrington, Col. 1, lines 40-52. Harrington utilized a post and pivot ball, receivable in a socket having a reduced diameter neck 57, for the specific purpose of preventing disassembly of the prosthesis.

Harrington also possesses a cavity in its annular shock absorbing member (68). Harrington, Col. 3, l. 58 – Col. 4, l. 12; Figure 2. By definition, this annular shock absorber has a central cavity. Indeed, this cavity is shown in Figure 2 with threaded post 46 extending therethrough.

Because Steffee directly teaches away from devices such as Harrington that contain additional connections between the upper and lower endplates, and because combining these references would render them unsatisfactory for their respective intended purposes, the combination is improper. Therefore the Harrington/Steffee/Cauthen combination (claims 44 and 128) and the Harrington/Steffee/Cauthen/Kenna combination (claim 45) and the Harrington/Steffee/Kenna/Wang combination (claim 129) are all improper.

For the sake of completeness it is noted that Cauthen and Kenna disclose spinal implants for intervertebral disc replacement, but both these references also fail to disclose any teaching of the Projection and Surface Limitations. They similarly do not change the fact that Harrington cannot be modified to remove the pivot ball and socket in order to

contain the Projection Limitation and the Surface Limitation. Therefore, even if the Harrington/Steffee/Cauthen combination or the Harrington/Steffee/Cauthen/Kenna combination were proper, which they are not, the combinations still fail to render obvious these claims.

Similarly, Wang, *et al.* teaches a prosthesis formed from a dispersion strengthened cobalt-chromium-molybdenum alloy. It also does not change the fact that Harrington cannot be modified to remove the pivot ball and socket in order to contain the Projection Limitation and the Surface Limitation. Accordingly, even if the Harrington/Steffee/Kenna/Wang combination were proper, which it is not, the combination still fails to render obvious these claims.

For at least the reasons set forth herein, the Applicants respectfully submit that the cited references fail to render obvious independent claims 32, 112, 119, and 133-135, and any claim depending therefrom. Thus, the Applicants respectfully request that this rejection be withdrawn.

New Claims

As stated above, claims 136-144 have been added, with claims 136, 141, and 144 being independent. Claim 136 recites an artificial intervertebral disc prosthesis comprising first and second endplates each having a first surface for engaging a vertebra and a second surface opposite said first surface; a longitudinal axis defined between said first endplate and said second endplate and normal thereto; an annular polymeric member having a cavity defining a polymeric member internal space that is bounded along a longitudinal axis by the second surfaces of the first and second endplates, and is bounded in a plane normal to said longitudinal axis by a polymeric member internal surface; and a

projection located within said polymeric member internal space having a contact surface at a distal end thereof for directly contacting a portion of said second surface of said first endplate. At least one of the adhesion layers bonding the polymeric member to the endplates is parallel to the contact surface of the projection. The cited references contain no such structure. Harrington's "adhesion layer"—if it had one—would be on the frustoconical surfaces. Harrington's equivalent "contact surface"—if it had one—would be at the distal ends of each frustoconical surface. The adhesion layer and the equivalent contact surface of Harrington are not parallel.

Dependent claims 137-140 merely add limitations to claims already discussed herein and allowable for the same reasons.

Claim 141 recites first and second endplates each having a first surface for engaging a vertebra and a second surface opposite said first surface; an annular polymeric member interposed between the first and second endplates and having a cavity defining a polymeric member internal space; and a projection extending from the second endplate into the polymeric member internal space toward the first endplate; wherein the annular polymeric member is adhered to the second endplate at an adhesion layer lying in an adhesion layer surface plane. The cited references contain no such structure. Harrington's "adhesion layer"—if it had one—would be the frustoconical surfaces. A frustoconical surface does not lie in a plane.

Claims 142-143 depend from claim 141 and add limitations thereto and are therefore allowable for the same reasons.

Claim 144 recites first and second endplates each having a first surface for engaging a vertebra and a second surface opposite said first surface; an annular polymeric

member interposed between the first and second endplates and having a cavity defining a polymeric member internal space; wherein each of said first endplate and second endplate comprises a respective centroid, and an axis intersecting said centroids is defined as a first axis; wherein a cross-sectional plane is defined containing said first axis; wherein in a section cut by said cross-sectional plane, on a left side there is a left contact interface line where said polymeric member contacts said first endplate second surface, and a left imaginary extension line of said left contact interface line projecting inwardly into said polymeric member internal space; wherein in said cross-sectional plane on a right side there is a right contact interface line where said polymeric member contacts said first endplate second surface, and a right imaginary extension line of said right contact interface line projecting inwardly into said polymeric member internal space; wherein said first endplate comprises a projection extending from said first endplate across said left imaginary extension line or said right imaginary extension line into said polymeric member internal space. The cited references do not disclose this structure. The projection of Harrington does not extend across either a left imaginary line extension of the left-most frustoconical section surface or a right imaginary line extension of the right-most frustoconical section surface.

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CONCLUSION

The Applicants respectfully submit that the application is in condition for allowance, and reconsideration and notice of allowance are respectfully requested. If the Examiner believes that prosecution might be advanced by discussing the application with the Applicants' counsel, in person or over the telephone, the Applicants' counsel would welcome the opportunity to do so.

Respectfully submitted,

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